



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|--------------------------|-------------------|------------------------|--------------|
| Substitute for form 1449A/PTO | | Complete if Known | | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/027115 | | |
| | | Filing Date | December 20, 2001 | | |
| | | First Named Inventor | Donald E. Ackley | | |
| | | Art Unit | 2828 | | |
| | | Examiner Name | Nguyen, Tuan N. | | |
| Sheet | 1 | of | 1 | Attorney Docket Number | BVTP-P01-029 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|--|--------------------------------|--|--|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|--------------------------------|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ² |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| TN | AA | DE 299 11 250 U1 | 11-25-1999 | Radchenko | | |
| TN | AB | EP 0 560 627-A2 | 09-15-1993 | De Beers Industrial Diamond | | |
| | | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|--------------------------|--|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | | | | | |
| TN | CA | Duthie, P.J. et al. Passively aligned four-channel reflective InP MQW modulator transmitter. Electronics Letters 31(14), 1177-1179 (6 July 1995). | | | |
| TN | CB | Wipiejewski, T. et al. Efficient Alignment Tolerant Coupling of Vertical-Cavity Lasers to Single-Mode Fibers. Proc. Euro. Conf. on Optical Comm. (ECOC), Zurich (12-16 Sept. 1993). | | | |
| | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|-----------------------|--------------------|--------------------|---------|
| Examiner Signature | <i>Tuan Nguyen</i> | Date Considered | 5/28/04 |
|-----------------------|--------------------|--------------------|---------|

RECEIVED
AUG -8 2003
TECHNOLOGY CENTER 2800

| | | | |
|--|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 11019-029001 | Application No. 10/027,115 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Donald E. Ackley | |
| | | Filing Date December 20, 2001 | Group Art Unit |

| U.S. Patent Documents | | | | | | | |
|-----------------------|-----------|---------------|------------|-----------------|-------|----------|----------------------------|
| Examiner Initial | Desig. ID | Patent Number | Issue Date | Patentee | Class | Subclass | Filing Date If Appropriate |
| TN | AA | 6,080,116 | 06/27/2000 | Erickson et al. | 600 | 573 | |
| | AB | 6,050,988 | 04/18/2000 | Zuck | 604 | 890.1 | |
| | AC | 5,883,211 | 03/16/1999 | Sassi et al. | 526 | 367.2 | |
| | AD | 5,879,326 | 03/09/1999 | Godshall et al. | 60A | 506 | |
| | AE | 5,876,675 | 03/02/1999 | Kennedy | 422 | 99 | |
| | AF | 5,865,786 | 02/02/1999 | Sibalis et al. | 604 | 20 | |
| | AG | 5,858,188 | 01/12/1999 | Soane et al. | 264 | 454 | |
| | AH | 5,852,495 | 12/22/1998 | Parce | 356 | 344 | |
| | AI | 5,848,991 | 12/15/1998 | Gross et al. | 604 | 140 | |
| | AJ | 5,843,114 | 12/01/1998 | Jang | 606 | 186 | |
| | AK | 5,807,375 | 09/15/1998 | Gross et al. | 60A | 890.1 | |
| | AL | 5,801,057 | 09/01/1998 | Smart et al. | 436 | 68 | |
| | AM | 5,697,901 | 12/16/1997 | Eriksson | 664 | 46 | |
| | AN | 5,658,515 | 08/19/1997 | Lee et al. | 264 | 219 | |
| | AO | 5,632,957 | 05/27/1997 | Heller et al. | 422 | 68.1 | |
| | AP | 5,618,295 | 04/08/1997 | Min | 606 | 171 | |
| | AQ | 5,611,942 | 03/18/1997 | Mitsui et al. | 216 | 67 | |
| | AR | 5,611,806 | 03/18/1997 | Jang | 606 | 167 | |
| | AS | 5,605,662 | 02/25/1997 | Heller et al. | 422 | 68.1 | |
| | AT | 5,591,139 | 01/07/1997 | Lin et al. | 604 | 264 | |
| | AU | 5,582,184 | 12/10/1996 | Erickson et al. | 600 | 576 | |
| | AV | 5,527,288 | 06/18/1996 | Gross et al. | 604 | 140 | |
| | AW | 5,457,041 | 10/10/1995 | Ginaven et al. | 435 | 455 | |
| | AX | 5,401,242 | 03/28/1995 | Yacowitz | 604 | 48 | |
| | AY | 5,383,512 | 01/24/1995 | Jarvis | 164 | 46 | |
| | AZ | 5,364,374 | 11/15/1994 | Morrison et al. | 604 | 272 | |
| | AAA | 5,335,670 | 08/09/1994 | Fishman | 600 | 556 | |

RECEIVED
MAR 14 2002
TECHNOLOGY CENTER 2000

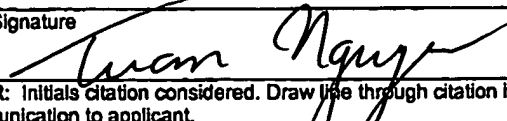
| | |
|--|----------------------------|
| Examiner Signature <i>Tran Nguyen</i> | Date Considered 5/28/04 |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|---------------------------------------|------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 11019-029001 | Application N. 10/027,115 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Donald E. Ackley | |
| | | Filing Date December 20, 2001 | Group Art Unit |

| U.S. Patent Documents | | | | | | | |
|-----------------------|-----------|---------------|------------|------------------|-------|----------|----------------------------|
| Examiner Initial | Desig. ID | Patent Number | Issue Date | Patentee | Class | Subclass | Filing Date If Appropriate |
| TN | ACCC | 3,086,530 | 04/23/1963 | Groom | 606 | 186 | |
| I | ADDD | 3,034,507 | 05/15/1962 | McConnell et al. | 604 | 46 | |
| I | AEEE | 2,893,392 | 07/07/1959 | Wagner | 604 | 47 | |

| Foreign Patent Documents or Published Foreign Patent Applications | | | | | | | | |
|---|-----------|------------------|------------------|--------------------------|-------|----------|-------------|----|
| Examiner Initial | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation | |
| | | | | | | | Yes | No |
| TN | AFFF | 7-132119 | 05/23/1995 | JP | | | X | |
| I | AGGG | 7-196314 | 08/01/1995 | JP | | | | |
| I | AHHH | EP 0 652 600 B1 | 04/28/1999 | EP | | | | |
| I | AIII | WO 93/17754 | 09/16/1993 | WIPO | | | | |
| I | AJJJ | WO 96/37256 | 11/28/1996 | WIPO | | | | |
| I | AKKK | WO 96/40365 | 12/19/1996 | WIPO | | | | |
| I | ALLL | WO 96/41236 | 12/19/1996 | WIPO | | | | |
| I | AMMM | WO 97/07734 | 03/06/1997 | WIPO | | | | |
| I | ANNN | WO 98/00193 | 01/08/1998 | WIPO | | | | |
| I | AOOO | WO 98/28037 | 07/02/1998 | WIPO | | | | |
| I | APPP | EP 0 497 620 B1 | 07/29/1998 | EP | | | | |
| I | AQQQ | DE 195 25 607 A1 | 01/16/1997 | Germany | | | | |
| I | ARRR | WO 98/00194 | 01/08/1998 | WIPO | | | | |
| I | ASSS | WO 98/28037 | 07/02/1998 | WIPO | | | | |
| I | ATTT | WO 98/00193 | 01/08/1998 | WIPO | | | | |
| I | AUUU | WO 99/64580 | 12/16/1999 | WIPO | | | | |

| Other Documents (include Author, Title, Date, and Place of Publication) | | |
|---|-----------|---|
| Examiner Initial | Desig. ID | Document |
| TN | AVVV | "101 Uses for Tiny Tubules", <i>Science</i> . Vol. 247, Part I, March 23, 1990 |
| I | AWWW | "Single-crystal whiskers," <i>Biophotonics International</i> p. 64 (November/December 1996) |

| | |
|--|----------------------------|
| Examiner Signature  | Date Considered 5/28/04 |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 11019-029001 | Application No. 10/027,115 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Donald E. Ackley | |
| | | Filing Date December 20, 2001 | Group Art Unit |

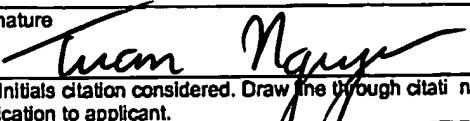
| U.S. Patent Documents | | | | | | | |
|-----------------------|-----------|---------------|------------|--------------------|-------|----------|----------------------------|
| Examiner Initial | Desig. ID | Patent Number | Issue Date | Patentee | Class | Subclass | Filing Date If Appropriate |
| TN | ABB | 5,279,552 | 01/18/1994 | Magnet | 604 | 47 | |
| | ACC | 5,279,544 | 01/18/1994 | Gross et al. | 604 | 20 | |
| | ADD | 5,250,023 | 10/05/1993 | Lee et al. | 604 | 20 | |
| | AEE | 5,138,220 | 08/11/1992 | Kirkpatrick | 313 | 309 | |
| | AFF | 5,054,339 | 10/08/1991 | Yacowitz | 81 | 9.22 | |
| | AGG | 5,035,711 | 07/30/1991 | Aoki et al. | 424 | 422 | |
| | AHH | 4,969,468 | 11/13/1990 | Byers et al. | 600 | 373 | |
| | AII | 4,921,475 | 05/01/1990 | Sibalis | 604 | 20 | |
| | AJJ | 4,798,582 | 01/17/1989 | Sarath et al. | 604 | 47 | |
| | AKK | 4,771,660 | 09/20/1988 | Yacowitz | 81 | 9.22 | |
| | ALL | 4,703,761 | 11/03/1987 | Rathbone et al. | 600 | 576 | |
| | AMM | 4,671,288 | 06/09/1987 | Gough | 600 | 347 | |
| | ANN | 4,664,651 | 05/12/1987 | Weinshenker et al. | 604 | 115 | |
| | AOO | 4,320,758 | 03/23/1982 | Eckenhoff et al. | 604 | 802.1 | |
| | APP | 4,222,392 | 09/16/1980 | Brennan | 600 | 556 | |
| | AQQ | 4,156,659 | 05/29/1979 | Barnhart | 376 | 323 | |
| | ARR | 4,109,655 | 08/29/1978 | Chacornac | 604 | 47 | |
| | ASS | 3,964,482 | 06/22/1976 | Gerstel et al. | 604 | 890.1 | |
| | ATT | 3,918,449 | 11/11/1975 | Pistor | 604 | 47 | |
| | AUU | 3,675,766 | 07/11/1972 | Rosenthal | 206 | 367 | |
| | AVV | 3,596,660 | 08/03/1971 | Melone | 604 | 47 | |
| | AWW | 3,556,080 | 01/19/1971 | Hein | 600 | 556 | |
| | AXX | 3,221,740 | 12/07/1965 | Rosenthal | 604 | 47 | |
| | AYY | 3,221,739 | 12/07/1965 | Rosenthal | 604 | 47 | |
| | AZZ | 25,637 | 09/08/1964 | Kravitz et al. | 126 | 31 | |
| | AAAA | 3,136,314 | 06/09/1964 | Kravitz et al. | 604 | 46 | |
| | ABBB | 3,123,212 | 03/03/1964 | Taylor et al. | 206 | 367 | |

| | |
|--|----------------------------|
| Examiner Signature <i>Man Nguyen</i> | Date Considered 5/28/04 |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 11019-029001 | Application No. 10/027,115 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Donald E. Ackley | |
| | | Filing Date December 20, 2001 | Group Art Unit |

Other Documents (include Author, Title, Date, and Place of Publication)

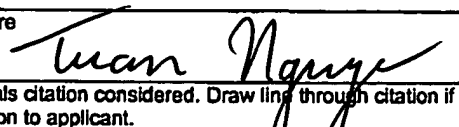
| Examiner Initial | Desig. ID | Document |
|------------------|-----------|--|
| TN | AXXX | Amsden et al., "Transdermal Delivery of Peptide and Protein Drugs: an Overview," <i>ALChE Journal</i> 41(8):1972-1997 (1995). |
| | AYYY | Bronaugh et al, <i>Percutaneous Absorption: Mechanisms, Methodology, Drug Delivery</i> , (1985) |
| | AZZZ | Brumlik et al. "Template Synthesis of Metal Microtubules" <i>J. Am. Chem. Soc.</i> 199, 113, 3174-3175 |
| | AAAAA | Despont, et al. "High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist For MEMS Applications" <i>Proc. of IEEE 10th Annual International Workshop on MEMS</i> , Nagoya, Japan pp. 518-522 (Jan. 26-30, 1997). |
| | ABBBB | Edell et al., "Factors Influencing the Biocompatibility of Insertable Silicon Microshafts in Cerebral Cortex" <i>Biomedical Engineering</i> Vol. 39(6) June 1992. |
| | ACCCC | Frazier et al., "Metallic Microstructures Fabricated using Photosensitive Polyimide Electroplating Molds," <i>Journal of Microelectromechanical Systems</i> Vol. 2(2):87-97, 1993 |
| | ADDDD | Frazier et al., "Two Dimensional Metallic Microelectrode Arrays for Extracellular Stimulation and Recording of Neurons", <i>IEEE Proceedings of the Micro Electro Mechanical Systems Conference</i> , pp. 195-200 (1993). |
| | AEEEE | Hadgraft & Guy, eds., <i>Transdermal Drug Delivery: Developmental Issues and Research Initiatives</i> (1989) |
| | AFFFF | Haga et al., "Transdermal iontophoretic delivery of insulin using a photoetched microdevice," <i>Journal of Controlled Release</i> 43 (1997) 139-149 |
| | AGGGG | Hashimi, et al., "Genetic Transformation of nematodes Using Arrays of Micromechanical Piercing Structures," <i>BioTechniques</i> 19(5):766-70 (1995) |
| | AHHHH | Henry et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery" <i>Journal of Pharmaceutical Sciences</i> Vol. 87, No. 8 (1998) |
| | AIIII | Henry et al., "Micromachined Needles For the Transdermal Delivery of Drugs" <i>IEEE Proceedings of Micro Electro Mechanical Systems 11th Annual International Workshop</i> Heidelberg, Germany pp. 494-98 (January 25-29, 1998) |
| | AJJJJ | Hoffert "Transcutaneous Methods Get Under the Skin," <i>The Scientist</i> 12 (1998). |
| | AKKKK | Jaeger, <i>Volume V Introduction to Microelectronic Fabrication</i> (1988) |
| | ALLLL | Jansen et al., "The Black Silicon Method IV: The Fabrication of Three Dimensional Structures in Silicon With High Aspect Ratios For Scanning Probe Microscopy and Other Applications," <i>IEEE Proceedings of Micro Electro Mechanical Systems Conference</i> , pp. 88-93 (1995) |
| | AMMMM | Laermer et al., "Bosch deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Application" <i>IEEE International MEMS '99 Conference on Micro Electro Mechanical Systems</i> (January 17-21, 1999) |
| | ANNNN | Langer, "Drug Delivery and targeting" <i>Nature</i> Vol. 392 Supp. April 30, 1998 pp. 5-10 |
| | AOOOO | Lehmann "Porous Silicon - A New Material For MEMS" <i>IEEE 9th Annual International Workshop on Micro Electro Mechanical Systems</i> (Feb. 11-15, 1996) |
| | APPPP | Lin, et al. "Silicon Processed Microneedles" <i>The 7th International Conference on Solid-State Sensors and Actuators</i> , 1993 |
| | AQQQQ | Martin et al., "Template Synthesis of Organic Microtubules," <i>J. Am. Chem. Soc.</i> 1990, 112, 8976-8977 |

| | |
|--|----------------------------|
| Examiner Signature  | Date Considered 5/28/04 |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|---------------------------------------|-------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket N . 11019-029001 | Application No. 10/027,115 |
| Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b)) | | Applicant Donald E. Ackley | |
| | | Filing Date December 20, 2001 | Group Art Unit |

| Other Documents (include Author, Title, Date, and Place of Publication) | | |
|---|-----------|---|
| Examiner Initial | Desig. ID | Document |
| TN | ARRRR | Najafi et al. "Strength Characterization of Silicon Microprobes in Neurophysiological Tissues," <i>IEEE Transactions on Biomedical Engineering</i> Vol. 37, No. 5 May 1990 |
| | ASSSS | Prausnitz, Mark R. "Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules" <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 14(4):455-483 (1997) |
| | ATTTT | Quan, "Researchers envision pain-free drug delivery: Plasma etch yields microneedle arrays" <i>Electronic Engineering Times</i> 63:63-64 (1998) |
| | AUUUU | Rai-Choudhury, ed., <i>Handbook of Microlithography, Micromachining, and Microfabrication</i> Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998 |
| | AVVVV | Reiss "Glucose-and Blood Monitoring Systems Vie for Top Spot" <i>Biophotonics Int'l</i> , pp.43-45 (May/June 1997) |
| | AWWWW | Runyan, et al. <i>Semiconductor Integrated Circuit Processing Technology</i> (1990) |
| | AXXXX | Schift, "Fabrication of replicated high precision insert elements for micro-optical bench arrangements" <i>Proc. SPIE - International Soc. Optical Engineer</i> 3513:122-134 (1998) |
| | AYYYY | Talbot et al. "Polymolding: Two Wafer Polysilicon Micromolding of Closed Flow Passages for Microneedles and Microfluidic Devices" <i>Solid State Sensor and Actuator Workshop</i> Hilton Head Island, South Carolina, June 8-11 266-268 (1988). |
| | AZZZZ | Trimmer et al. "Injection of DNA into Plant and Animal Tissues with Micromechanical Piercing Structures" <i>IEEE Proceedings of Micro Electro Mechanical Systems Conference</i> , pp. 111-15 (1995) |
| | AAAAAA | Weber et al., "Micromolding - a powerful tool for the large scale production of precise microstructure," <i>Proc. SPIE - International Soc. Optical Engineer</i> 2879:156-167 (1996). |
| | ABBBBB | Zuska, "Microtechnology Opens Doors to the Universe of Small Space" <i>Medical Device and Diagnostic Industry</i> , p. 131 (1997). |

RECEIVED
 MAR 14 2002
 TECHNOLOGY CENTER 2800

| | |
|--|----------------------------|
| Examiner Signature  | Date Considered 5/28/04 |
| EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |